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Does practice make perfect?

The hospital volume-outcome association in the context of quality and patient safety for total hip arthroplasty

Unni J Trondsen

Master Thesis in Public Health Science

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The Norwegian University of Life Sciences (NMBU)

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This work marks the end of a long ongoing education in infection control, since I started in my first year at Nordic School of Public Health (NHV, Gothenburg) in 2009, which I now complete at NMBU. I want to thank both my former and present leader and colleagues at Innlandet Hospital Trust (SI HF) and in SI HF division Tynset, where I am located.

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Preface

This paper is a Master Thesis in Public Health Science, delivered within department of Chemistry, Biotechnology and Food Science, at the Norwegian University of Life Sciences (NMBU).

Sammendrag av artikkel

Denne masteroppgaven ble skrevet som en artikkel med en kappe som danner grunnlaget for artikkelen, kappen inkluderer en utvidet teoribakgrunn og diskusjon.

Introduksjon: Infeksjon i operasjonsområdet (POSI) er blant de hyppigste helsetjenesteassosierte infeksjoner (HAI), en vanlig komplikasjon og uønsket hendelse etter hofteprotese, og en velkjent kvalitetsindikator i sykehus. Flere pasient-, prosedyre- og sykehusrelaterte faktorer, som kirurgisk volum, kan påvirke risikoen for å utvikle en infeksjon i operasjonsområdet (SSI) etter primær total hofteproteseinngrep (THA).

Mål: Undersøke sammenhengen mellom kirurgisk volum og risiko for SSI etter THA.

Design: Deskriptiv kohort-studie, basert på prospektive nasjonale overvåkingsdata

Metode: Vi brukte overvåkingsdata for THA fra Norsk overvåkingssystem for antibiotikabruk og helsetjeneste-assosierte infeksjoner (NOIS), for perioden 1. september 2012 til 30. april 2016. Multivariat og multilevel analyse estimerte mulige sammenhenger mellom både sykehusvolum og andre variabler, og risiko for infeksjoner i operasjonsområdet etter THA. Den justerte Odd ratio (OR) ble beregnet for sykehusvolum for THA prosedyrer, stratifisert i tre sykehusvolumgrupper: ≤150, 150-299, ≥300.

Resultat: Totalt ble det inkludert 29746 THA fra 53 private og offentlige sykehus. Vi fant en nesten statistisk signifikant sammenheng mellom et årlig sykehusvolum på 150 til 299 THA og en lavere risiko for dype infeksjoner i operasjonsområdet.

Konklusjon: Kirurgisk volum i seg selv kan antagelig ikke beskrive kvalitet og pasientsikkerhet eller forutsi kirurgiske utfall som SSI etter THA. Kirurgisk volum kan, som en indikator for uønskede hendelser og en «proxy» målingsenhet for andre risikofaktorer, muligens bidra til å identifisere forbedringsområder.

Nøkkelord: Sykehusvolum, hofteprotese, infeksjoner i operasjonsområdet, infeksjonskontroll

Summary of Article

This master thesis is written as a journal article with a "kappe" (Norwegian concept) as a basis. The "kappe" includes more detailed explanations, an expanded background theory and discussion of the article's findings.

Introduction: Surgical site infection (SSI) is among the most frequent healthcare- associated infections (HAIs) worldwide, and a well-known indicator of quality and safety in hospitals. Several patient-, procedure- and hospital related factors may be of importance to the association between surgical volume and SSI after primary total hip arthroplasty (THA).

Objective: Examine any association between hospital volume and the risk of SSI after THA.

Design: Descriptive cohort-study based on prospective national surveillance data.

Methods: We used surveillance data for THA procedures from the Norwegian Surveillance System for Antibiotic Consumption and Healthcare-associated Infections (NOIS), for the period of September 1st 2012 to April 30th 2016. Multivariate and multilevel analysis estimated any associations between both hospital volume and other co-variables, and the risk of SSIs after THA. The adjusted Odd ratio (OR) was estimated for the hospital volume of THA procedures, stratified in three hospital volume groups: $\leq$150, 150 to 299, $\geq$300.

Results: A total of 29746 THA procedures were included from 53 hospitals. We found a borderline significant association between an annual hospital volume of 150 to 299 THA procedures and a lower risk of deep SSI.

Conclusions: Hospital volume in itself can presumably not describe quality and patient safety or predict surgical outcomes such as SSI after THA procedure. As an indicator for adverse events and a proxy measure for other risk factors, hospital volume may help to identify areas of improvement.

Key words: Hospital volume, hip arthroplasty, hip replacement, surgical site infection, infection control.

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List of Abbreviations

ASA - Physical status score classification developed by the American Society of Anesthesiology

CI - Confidence Interval

CoNS - Coagulase negative staphylococci

ECDC - The European Centre for Disease Prevention and Control

HA - Hemiarthroplasty

HAI – Healthcare-Associated Infection

ICP - Infection Control Practitioner

IKP - Infection Control Program (IKP - Norwegian acronym)

MRSA - Methicillin-Resistant Staphylococcus aureus

NIPH - Norwegian Institute of Public Health

NNIS - Procedure Specific SSI Risk Index System calculating the patient's risk category for acquiring SSI after surgery, based on wound contamination class, duration of operation and ASA physical status score.

NOIS - The Norwegian Surveillance System for Antibiotic Consumption and Healthcare – associated Infections (NOIS - Norwegian acronym)

NPR - Norwegian Patient Record

OR – Odds Ratio

SAMDATA - comparison data for the specialist health services (SAMDATA - Norwegian acronym)

SSI – Surgical Site Infection

S. aureus - Staphylococcus aureus

THA – Total Hip Arthroplasty

WHO - World Health Organization

1. Introduction

Total hip arthroplasty (THA) is a common procedure worldwide, known to improve the patient's quality of life, relieve pain and improve function and mobility (1-4). It is also a surgical procedure with a risk of adverse events like surgical site infections (SSIs), that can lead to serious consequences for the patient and the health care personnel, and increased socioeconomic cost (1, 5-7). About 8000 THAs were performed in Norwegian hospitals in 2015. Norway's population is getting older and more likely to experience a hip fracture or the need to replace a worn hip by THA (5, 8, 9).

SSI is among the top three most frequent healthcare-associated infections (HAIs) and an indicator of quality and safety in hospitals (6, 10, 11). SSI remains one of the most common and serious adverse events after hip arthroplasty (12, 13), and effective infection control is one of several initiatives for preventing SSIs and promote public health (8, 14-16).

Factors which may influence the risk of SSI is the experience of the surgeon and the quality and organization of hospital services, and both surgeon and hospital volume are seen as proxy measures for other factors that may influence the outcome in surgical care (17-19).
Research about the hospital volume-outcome association has been of interest since the 1980's and is of growing interest for health providers, patients and politicians (17). The hospital volume-outcome association has been studied with varied results, and some studies show an association while others do no (11, 17-24). Both hospital and surgeon volume are of interest in this study, as they are both suggested to be good indicators for adverse events and associated with risk of SSI after THA (18, 19, 23) . We made an effort to include surgeon volume, but for several reasons we only have data for hospital volume. Many factors may explain the association between hospital volume and risk of SSI after THA.

As there is a lack of data for quality in health care processes, it is suggested that adjusted outcome data in clinical care is the best way to measure the quality of care (17). This requires access to comparable and quality assured data (6, 17). In this study we use national surveillance data for SSIs after THA from the Norwegian Surveillance System for Antibiotic Consumption and Healthcare –associated Infections (NOIS, Norwegian acronym) (10).

The objective of this study is to investigate if hospital volume of primary THA is associated with the risk of SSI, in order to identify potential areas of improvement.

In the background chapter we describe briefly a Volume-Outcome Relationship model and a framework for Quality and Patient Safety, hip arthroplasty, SSI definitions, and pathogenesis, diagnostics, microbiology and risk factors for SSIs, and infection control and management of SSIs.

2. Background

2.1 Quality, Patient Safety and the Volume- Outcome Association

Charles Vincent defines quality of care in light of the World Health Organization's (WHO) definition of effective health coverage, expressing a diversity of clinical, economic, political and other factors. He then defines quality of care as "the proportion of potential health gain actually delivered by healthcare organizations for its sets of patient, where the quality reflects the gap between what can be achieved and what actually happens" (25) .

Adverse event is the most ordinary term of harm in patient safety. Patient safety is defined by Vincent as "the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare" (25). Vincent defines adverse events as:

> *An unintended injury caused by medical management rather than by the disease process and which is sufficiently serious to lead to prolongation of hospitalisation or to temporary or permanent impairment or disability to the patient at time of discharge or both, (25).*

A large proportion of adverse events are related to surgery, where SSIs are the second largest group (6), and one of the most common adverse events and serious complications after hip arthroplasty (12). The report "Crossing the Quality Chasm" specifies safety as one of six aims of quality improvements in healthcare, where safety is presented as a system property (26). In order to interpret and compare findings and studies, it is important to be able to compare results and adverse event (6, 17).

In this study hospital volume is defined as the number of primary THA procedures performed at each hospital. Hospital volume can reflect the hospitals collective experience with a procedure to maintain a good quality of treatment (27). Surgeon volume may describe the amount of procedures performed by each surgeon in the hospitals, and may say something about the experience needed to offer an adequate quality of treatment (27). Hospital and surgeon volume are suggested as the best indicators for adverse events after THA, and as such, for quality and patient safety, and may also be seen as proxy measures for other risk factors that may influence the outcome in surgical care (17-19). Several studies have examined the hospital volume–outcome association with various results (5, 17, 19, 20, 23, 24, 28).

The Norwegian Health- and Hospital Plan (2016-2019) recommends that both hospital and surgeon volume must show an adequate number of procedures (8). Different literature suggests that surgeons should operate at least 20-50 joint replacements per year (21, 24, 29), or perform 25-30 of the same surgical procedures (9, 30, 31). A Danish report recommends a minimum annual surgeon volume of 70 – 100 procedures within each surgical specialty, with units of at least three specialists within each specific surgical procedure, to ensure quality (31).

Hewitt's model, called "Interpreting the Volume-Outcome Relationship in the Context of Health care Quality", visualizes several factors that may influence any association between volume and outcome in the specific processes of care (17)

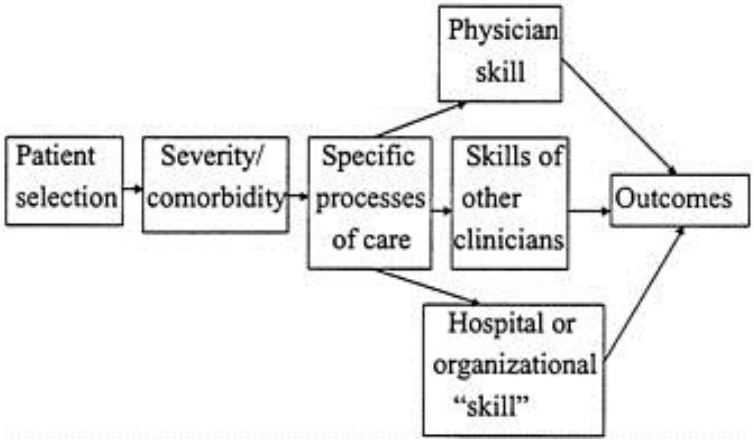

Figure 1: Conceptual Framework: How Could Volume Affect Quality (17)?

Vincent, Taylor-Adams and Stanhope's "Framework for Analysing Risk and Safety in Clinical Medicine" lists various factor types that may be essential for risk and safety assessment in clinical

care; “the patient, task and technology, individual (staff), team, work environment, organizational and management, and institutional context factors” (6, 32, 33).

2.2 Hip Arthroplasty

Primary hip arthroplasty, also called hip replacement, refers to the first time of replacing damaged parts or the whole hip joint by a prosthesis. This surgery is performed for achieving mobility and ease of pain, often caused by osteoarthritis, inflammatory joint disease, fractures, sequelae after hip fracture, septic femoral head necrosis or sequelae after childhood hip disease (Figure 1) (1). Hip replacement is performed both as THA and hemiarthroplasty (HA).

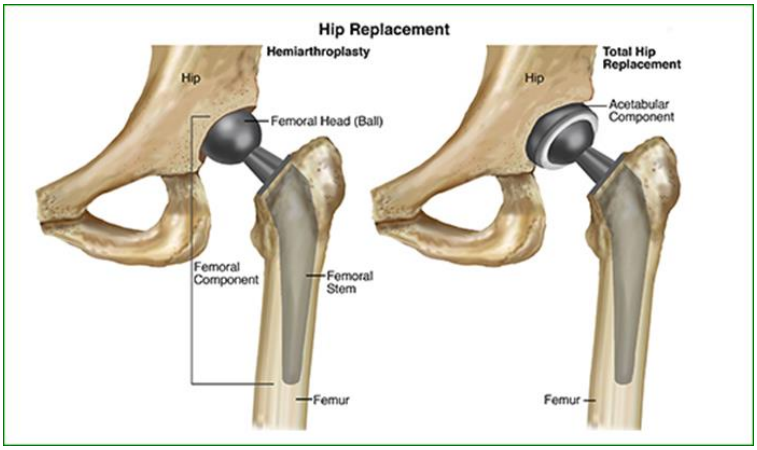

Figure 2: Hemiarthroplasty (HA) versus Total Hip Arthroplasty (34).

THA surgery removes and replaces both the femoral part of the hip joint and the acetabular cartilage, whereas hemiarthroplasty only remove and replace the femoral part by a prosthesis (1).

2.3 Surgical Site Infection

SSI is a common adverse events and a serious complication after hip arthroplasty, along with instability, aseptic loosening, peri-prosthetic fracture and sometimes death (12, 13, 35). Most SSIs are detected after discharge, within 90 days after surgery (36-38).

Deep SSI (i.e. deep incisional and organ/space) and superficial SSI may give different consequences and require different treatment, with a range from superficial wound care to revision surgery and also removal of the implant (1).

The costs of treating patients with SSIs after hip arthroplasty are divided between readmission to hospital, reoperation, and prolonged hospital stay (7, 13), where deep SSI are most costly (7, 13). A cost analysis of Norwegian data finds that superficial SSIs give 2.8 longer hospital stay and costs NOK 20.352, whereas the overall cost for deep SSI is NOK 407.487 (7). SSI also causes more use of antibiotics and the need for rehabilitation (13).

The Norwegian patient safety program "In Safe Hands 24-7, strategy 2014 – 2018" (39) aims to reduce the proportion of deep SSIs among all THA by 25 %. Quality improvement, efficiency and competence for achieving patient safety are of high priority in health care politics (8).

2.3.1 Definition Criteria of SSI

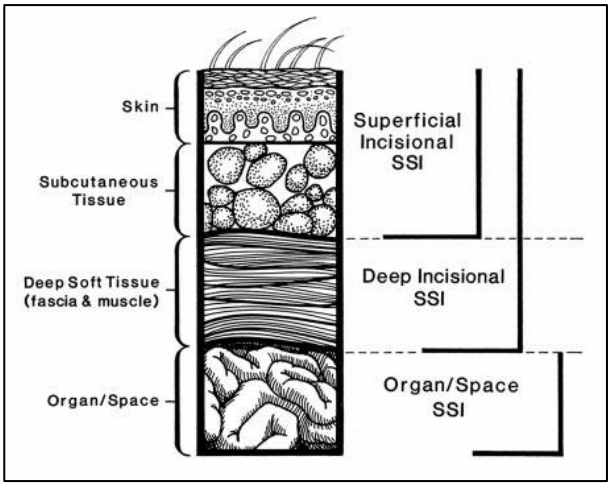

Figure 3: Schematic of SSI Anatomy and Appropriate Classification (40).

ECDC's SSI definitions are based on previously established definitions by the Centers for Disease Control and Prevention (CDC, USA) (41).

Definitions of SSIs (40-42)

Superficial incisional

Infection occurs within 30 days after the operation and infection involves only skin and subcutaneous tissue of the incision and at least one of the following:

- *Purulent drainage with or without laboratory confirmation, from the superficial incision.*
- *Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.*

- *At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.*
- *Diagnosis of superficial incisional SSI made by a surgeon or attending physician.*

Deep incisional

Infection occurs within 30 days after the operation if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissue (e.g. fascia, muscle) of the incision and at least one of the following:

- *Purulent drainage from the deep incision but not from the organ/space component of the surgical site.*
- *A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38ºC), localized pain or tenderness, unless incision is culture-negative.*
- *An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.*
- *Diagnosis of deep incisional SSI made by a surgeon or attending physician.*

Organ/Space

Infection occurs within 30 days after the operation if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (e.g. organs and spaces) other than the incision which was opened or manipulated during an operation AND at least one of the following:

- *Purulent drainage from a drain that is placed through a stab wound into the organ/space.*
- *Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.*
- *An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.*
- *Diagnosis of organ/space SSI made by a surgeon or attending physician.*

2.3.2 Pathogenesis, Diagnostic and Microbiology of SSI

In spite of all risk factors, the most common cause of all kinds of infections is microbial contamination in non-normal flora areas (43, 44). Microbial contamination and bacteria binding to the surface of the foreign body is essential for a deep infection to occur in implant surgery (45). Surgery with insertion of a foreign body generally contributes to a reduced infection defense and low infective dose, and even low virulent microbes may cause an infection (45). Biofilm often occurs and protects the microbes from the patient's immune system and antimicrobials, which makes the infection difficult to treat (45, 46).

Infections associated with hip arthroplasty are probably mainly acquired during surgery, especially for early infections (show symptoms of SSI within 3 months after surgery) and delayed infections (show symptoms of SSI between 3-24 months after surgery), whereas late infections (show symptoms of SSI more than 24 months after surgery) seem to be haematogenous with respiratory tract, skin, dental and urinary tract infections as the most common sources (5, 46-49). Superficial SSIs may cause or develop into a deep or organ/space SSI (47, 50, 51), showing the importance of surveillance for both superficial and deep SSIs (52). Superficial SSI is also seen as an expression of postoperative treatment and wound care, rehabilitation stay and the patient's own hygienic care (36).

Clinical diagnostics are often based on symptoms and local findings in the surgical site area. Tests and microbial diagnostics are essential for clinical diagnostics and treatment, where multiple samples are necessary (49).

A study using data from the Norwegian Arthroplasty Register investigated bacterial findings after revision of infected THAs in Norway (53). They found a distribution of microbes where 60 % of the infected THAs were caused by staphylococci (i.e. Coagulase negative staphylococci (CoNS) and *Staphylococcus aureus (S. aureus))*, 11 % by streptococci, 9 % by enterococci, 6 % by Gram-negative bacteria, 4 % by other microbes, and 10 % were polymicrobial. CoNS were associated with early, delayed and late infections, while S. aureus appeared mostly in early SSIs (53). Most commonly type of microbe causing SSI may be different for HA and THA, and it may also be different for superficial and deep SSIs after hip arthroplasty (54).

2.3.3 Patient-, Procedure- and Hospital- Related Risk Factors for SSI

Various conditions affecting the patient's immune system, or associated with longer hospital stay and complications, are likely to contribute to a higher risk of SSI after surgery (5). Comorbidities are reflected by ASA (classification of physical status score developed by the American Society of Anesthesiology (42, 55) and gives a picture of the patients overall health condition (5, 55). Socio-economic factors such as in inadequate health literacy and hard life conditions are mentioned as related to higher SSI risk (5). Colonization, especially with methicillin-resistant Staphylococcus aureus (MRSA), or previous infections are shown to increase risk of SSI after orthopedic surgery (5).

High age increases the risk of SSIs, probably due to reduced immune system and comorbidities (5, 56) Acute surgery is also shown to increase the risk of SSIs (1). Other patient related risk factors like sex may be due to differences in microbial colonization of the skin, and different studies vary in men or women having the highest risk (47, 56). Obesity is correlated to prolonged wound drainage and is another indicator for high risk of SSI after THA (5, 54).

Several procedure related risk factors such as preoperative hair shaving, prolonged or short duration of surgery and wounds classified at unclean probably influence the incidence of SSI after orthopedic surgery (44, 54, 57). National Nosocomial Infections Surveillance (NNIS) is a procedure specific SSI risk index system, and calculates the patient's risk for acquiring SSI after surgery, based on wound contamination class, duration of operation and ASA physical status score (55). NNIS $\geq$ 1 or 2 is found to be an independent factor for SSI (50, 58).

Prophylactic antimicrobial therapy is well known to decrease risk of SSIs, and prosthesis techniques involving hybrid fixation and cement without antibiotics are shown to increase the risk of revision due to SSIs (21, 47, 56, 59). Best practice in surgical technique is suggested to influence the incidence of SSI, which includes preventing tissue trauma, poor hemostasis, hypothermia and poor drainage (44). Saleh et al confirm an association between deep and superficial SSIs, where superficial SSI may be caused by postoperative hematoma and drainage (47, 51). Postoperative management of the surgical wound (incision care) are also associated with risk of SSI (44).

Hospital related risk factors such as extended pre- and postoperative stay in hospital may be related to a higher risk of SSI (58). Air quality in the operating room is mentioned as of significance for SSI risk and is probably affected by ventilation system, traffic and colonized or infected personnel (44). Surgeon and hospital volume are associated with risk of SSI after THA (19, 23), as indicators for adverse events after hip arthroplasty (18) and proxy measures for other risk factors that can affect outcomes such as SSIs (11, 17, 19). In a study be Geubbels et al they found no important association between hospital type and hospital size and the risk of SSI after THA (20).

2.3.4 Infection Control and Management of SSI

Infection control is the basis of preventing HAIs like SSIs, with the purpose of ensuring safe surgery and quality in every aspect of surgical patient care (44). Healthcare institutions in Norway are required to implement an infection control program (IKP - Norwegian acronym) (16). An IKP includes guidelines for infection control to ensure quality and safe performance for both patients and staff, and a surveillance system for HAIs. Infection surveillance is a key in infection control for targeted improvement in quality and safety (16, 42, 60). The SENIC-study by Haley et al described effective infection control, which include implemented infection surveillance with active feedback to the surgeons, with preventive activities and policies in clinical care supervised by infection control practitioners (61).

In a review, Zingg et al identified these factors for implementing effective infection control and infection surveillance (62);

> *1) Organisation of infection control at hospital level, 2) ward occupancy and workload, 3) materials, equipment and ergonomics, 4) use of guidelines, education and training, 5) team-oriented and task-oriented education and training, 6) standardization and audits, 7) prospective surveillance, feedback and networks, 8) development og multimodal strategies and tools, 9) identification and engagement og strategy champions, 10) creating a positive organizational culture.*

3. Objective

The aim of this study was to examine any association between hospital volume and the risk of surgical site infections after primary total hip arthroplasty, in order to identify potential areas of improvement.

4. Material and Methods

4.1 Data source

We used data from NOIS in this study (10, 42). Surveillance in NOIS has been continuous and mandatory since September 1st 2012. NOIS data from five different surgical procedures are submitted from 54 hospitals, both private and public, where THA procedure is one procedure (10, 63). Every four month, data are submitted to a national database at the Norwegian Institute of Public Health (NIPH). National data are quality assured both with validation rules upon import and manual checks. The following risk, background and outcome variables are collected through NOIS; sex and age, dates of admission, surgery and discharge, type of arthroplasty, wound contamination, preoperative antibiotic prophylaxis, elective or acute procedure, first SSI and last follow up, type of SSI, reoperations or readmissions due to SSIs or other, and hospital affiliation (10).

NOIS data is collected and quality checked in each hospital by surgeons and the infection control practitioners (64). Data on SSI status is collected at hospital level at discharge, and by a patient questionnaire within 30 days after surgery (10, 64). After discharge, SSIs are confirmed by the patient's general practitioner or by hospital outpatient physicians. Since 2012, NOIS does not follow up SSIs beyond 30 days after surgery (37).

4.2 Study population

This study includes national surveillance data of patients undergoing primary THA surgery between September 1st 2012 and April 30th 2016 with NCSP[1] codes NFB20, NFB30 and NFB40.

[1] NOMESCO Classification of surgical procedures

4.3 Outcome variable

The outcome of interest was physician confirmed SSI. All SSIs are identified in accordance with standardized European definitions of SSI following established definitions by the Centers for Disease Control and Prevention (CDC) (10, 41, 42). We investigated two outcomes; deep SSIs (deep incisional and organ/space) and superficial SSIs.

4.4 Hospital volume

Hospital volume is defined as the annual median number of primary THA procedures performed in each hospital, and in this study primary THA is referred to as THA. Surgeon volume is defined as the number of procedures performed by each surgeon in each hospital.

We used NOIS data to calculate a median annual hospital volume where we took into account possible seasonal variations, missing data submission or cessation of THA procedure. For 2012 and 2016 was only data from four months available. We calculated therefore a median hospital volume for those two years based on the complete year for each hospital. Regarding the cut offs for hospital volume groups we did not find any recommendations in the literature. We made an equal distribution of the number of THA procedures in each hospital volume group, to gain statistical power. Cut offs were set for hospital volume groups at <150, 150-299 and ≥300 procedures. Our hospital volume data complies with Norwegian Patient Register (NPR - Norwegian acronym).

4.5 Co-variables

All available risk variables in NOIS were considered for inclusion in the models. Following patient and procedure related variables were included; age, sex, NNIS risk index score, antibiotic prophylaxis, elective/acute surgery, fixation method, and preoperative length of stay (LOS). Structural variables included were hospital type, health care region and hospital size (beds). Hemiarthroplasty (HA) volume was included as a continuous variable.

Our data showed that more than 80 % of THA procedures are performed on patients older than 60 year and thus we selected these subgroups; 0-59, 60-69, 70-70 and 80+. Hospital type was categorized in strata of primary, secondary, tertiary and specialized units by definitions from the ECDC (42), corresponding with a national classification of hospitals by the Norwegian Directory

of Health (Comparative data for specialist health services - SAMDATA) (65). Hospital size was stratified by each hospital's number of beds, set to the closest 100 beds, following the ECDC's definition of hospital size (42). Key data for effective hospital beds from SAMDATA 2008 and 2013 were used, with effective beds defined as the annually adjusted average number of available beds (66, 67).

Data was quality assured and manually coded at the author's best effort when it was not readily available in the NOIS data, with reservation for any errors.

4.6 Data analysis

We performed separate analyses for superficial and deep SSIs by hospital THA volume group. Bivariate analysis was used to describe characteristics of hospitals, patients and procedure variables by hospital THA volume group. We calculated crude and adjusted odd ratio (OR), with 95 % confidence interval (CI) and $p>0.05$ as the statistical threshold, using logistic regression. The lowest volume group was set as reference in all analyses.

To model the variations between hospitals, we used multilevel logistic regression with two levels (procedure and hospital) in the final multilevel analysis. All co-variables were included in the final model. All analyses were performed using STATA/SE statistical software package version 14.0 for Windows (StataCorp LP).

4.7 Ethics

Consent for using de - identified NOIS data in this study was granted by the Data Protection Official at NIPH (68). NOIS is a national health registry with anonymous data, and is governed by a separate NOIS registry regulation and does not require patient consent (68).

5. Results

Altogether, 29746 THA procedures from 53 hospitals were included in this study. Median number of primary THA procedures in Norwegian hospitals for the period of September 1st 2012 and April 30th 2016 are 128.

As shown in table 1 the surgical volume by number of hospitals is stable over the years. A range of 47-50 hospitals delivered data to NOIS during the study period, with an annual total of approximately 8000 THA procedures.

Table 1 Number of participating hospitals (primary total hip arthroplasty procedures) reported in Norway between September 1st 2012 and April 30th 2016

	Annual hospital volume			
Year	Total	<150	150-299	≥300
2012 (September-December)	48 (2681)	31 (957)	10 (764)	7 (960)
2013	50 (7804)	31 (2579)	12 (2288)	7 (2937)
2014	50 (7874)	31 (2585)	12 (2473)	7 (2816)
2015	50 (8225)	31 (2710)	12 (2461)	7 (3054)
2016 (January-April)	47 (3162)	28 (1025)	12 (954)	7 (1183)

The highest incidence proportion of deep SSI is in age ≤80, NNIS risk index score 2&3 and in non-elective procedures, in tertiary hospitals, hospitals sized over 350 beds and the Middle region (table 2). Specialist hospitals, hospitals sized fewer than 151 beds, and the Western health care region has the lowest incidence proportion of deep SSIs (table 2).

Risk factors presented in table 2 were examined by multivariate and multilevel analysis (table 3a and 3b). Multilevel analysis show a higher risk of developing deep SSI after THA procedure in the following confounders; male gender with an OR of 1.6, age ≥80 year with an OR of 1.8, NNIS risk index >1with an OR of 1.7 and NNIS risk index ≥2 with an OR of 2.3, all statistically significant. A lower risk of developing deep SSIs after THA is found in health care region West with a statistically significant OR of 0.4 (table 3b).

For superficial SSIs we found the following to be statistically significant in multilevel analysis (table 3a): NNIS risk index >1with an OR of 1.8 and NNIS risk index ≥2 with an OR of 3.5, showing a higher risk of developing SSI after THA procedure. Specialist hospitals show a statistical significant lower risk of developing superficial SSIs after THA procedure (table 3b) with an OR of 0.1

Table 2 Number and incidence proportion of surgical site infections by patient, procedure, demographic and structural variables after primary total hip arthroplasty procedures, reported in Norway between September 1st 2012 and April 30th 2016

	Deep SSIs		Superficial SSIs	
Variable	No.	%	No.	%
Overall	314	1.1	307	1.0
Age				
0-59	53	0.9	49	0.8
60-69	85	0.9	104	1.1
70-79	115	1.2	107	1.1
80+	61	1.4	47	1.1
Sex				
Female	160	0.8	194	1.0
Male	154	1.5	113	1.1
NNIS risk index				
0	182	0.9	168	0.8
1	110	1.5	102	1.4
2 & 3	18	2.0	23	2.6
Elective				
Yes	289	1.0	16	0.8
No	25	1.3	291	1.0
Fixation method				
Cemented	101	1.1	85	1.0
Non cemented	84	1.0	120	1.4
Hybrid	129	1.0	102	0.8
Ab prophylaxis				
Yes	287	1.0	280	1.0
No	11	1.4	10	1.3
LOS				
0	136	1.1	145	1.2
1	139	0.9	134	0.9
≥ 2	38	1.2	28	0.9
Region				
South-east	194	1.1	154	0.8
West	36	0.7	39	0.7
Middle	64	1.5	72	1.7
North	20	1.0	42	2.2
Hospital type				
Primary	146	0.9	146	1.1
Secondary	74	1.1	100	1.4
Tertiary	71	1.4	51	1.0
Specialist	16	0.4	4	0.1
Private	7	1.1	6	0.9
Hospital size				
1-150	106	0.9	119	1.0
151-350	111	1.1	102	1.0
350+	97	1.3	86	1.1

Table 3a Risk of surgical site infection by patient and procedure variables, reported in Norway between September 1st 2012 and April 30th 2016

	Deep surgical site infections		Superficial surgical site infections	
Variable	Crude OR (95% CI)	Adjusted OR* (95% CI)	Crude OR (95% CI)	Adjusted OR* (95% CI)
Age				
0-59	*Ref*	*Ref*	*Ref*	*Ref*
60-69	1.0 (0.7-1.3)	0.9 (0.7-1.4)	1.3 (0.9-1.8)	1.3 (0.9-1.9)
70-79	1.3 (0.9-1.8)	1.2 (0.9-1.8)	1.3 (0.9-1.8)	1.3 (0.9-1.9)
≥80	1.6 (1.1-2.3)	1.5 (1.0-2.3)	1.3 (0.9-2.0)	1.3 (0.8-2.0)
Sex				
Female	*Ref*	*Ref*	*Ref*	*Ref*
Male	1.8 (1.4-2.3)	1.8 (1.5-2.3)	1.1 (0.9-1.4)	1.1 (0.9-1.4)
NNIS risk index				
0	*Ref*	*Ref*	*Ref*	*Ref*
1	1.7 (1.3-2.1)	1.5 (1.1-1.9)	1.7 (1.3-2.1)	1.8 (1.4-2.4)
≥2	2.3 (1.4-3.8)	2.0 (1.2-3.5)	3.2 (2.1-5.0)	3.5 (2.1-5.7)
Fixation method				
Cemented	*Ref*	*Ref*	*Ref*	*Ref*
Non cemented	0.9 (0.6-1.2)	0.9 (0.6-1.4)	1.5 (1.1-2.0)	1.4 (1.0-2.1)
Hybrid	0.9 (0.7-1.2)	1.2 (0.9-1.7)	0.9 (0.7-1.2)	0.9 (0.6-1.3)
Antibiotic prophylaxis				
No	*Ref*	*Ref*	*Ref*	*Ref*
Yes	0.7 (0.4-1.3)	0.8 (0.3-2.0)	0.8 (0.4-1.5)	0.7 (0.3-2.0)
Elective procedure				
No	*Ref*	*Ref*	*Ref*	*Ref*
Yes	0.8 (0.5-1.2)	1.1 (0.7-1.7)	1.3 (0.8-2.1)	1.5 (0.9-2.6)
Preoperative length of stay				
0 days	*Ref*	*Ref*	*Ref*	*Ref*
1 day	0.8 (0.6-1.0)	0.9 (0.7-1.3)	0.7 (0.6-0.9)	0.9 (0.7-1.2)
≥2 days	1.1 (0.7-1.5)	1.0 (0.6-1.5)	0.7 (0.5-1.1)	1.6 (0.7-1.8)

*Level 1: age, sex, NNIS risk index, fixation, antibiotic prophylaxis, hemiarthroplasty volume, elective/acute surgery, preoperative length of stay, hospital size, region, hospital type and surgical volume. Level 2: hospital

Table 3b Association between the risk of surgical site infection and demographic, structural and continuous variables, reported in Norway between September 1st 2012 and April 30th 2016

	Deep surgical site infections		Superficial surgical site infections	
Variable	Crude OR (95% CI)	Adjusted OR* (95% CI)	Crude OR (95% CI)	Adjusted OR* (95% CI)
Hospital size (beds)				
≤150	*Ref*	*Ref*	*Ref*	*Ref*
151-350	1.2 (0.9-1.5)	1.1 (0.7-1.9)	0.9 (0.7-1.2)	0.6 (0.3-1.1)
>350	1.4 (1.1-1.9)	1.1 (0.4-3.1)	1.1 (0.8-1.5)	0.7 (0.2-2.4)
Region				
South-East	*Ref*	*Ref*	*Ref*	*Ref*
West	0.6 (0.4-0.9)	0.4 (0.2-0.7)	0.9 (0.6-1.2)	0.7 (0.4-1.3)
Middle	1.4 (1.1-1.9)	1.0 (0.6-1.6)	2.0 (1.5-2.7)	1.7 (1.0-3.1)
North	1.0 (0.6-1.6)	0.7 (0.4-1.4)	2.6 (1.9-3.7)	1.5 (0.8-2.9)
Hospital type				
Primary	*Ref*	*Ref*	*Ref*	*Ref*
Secondary	1.0 (0.7-1.3)	0.9 (0.5-1.5)	1.3 (1-0-1.7)	1.9 (1.0-3.8)
Tertiary	1.3 (1.0-1.8)	1.7 (0.7-4.3)	1.0 (0.7-1.3)	1.2 (0.4-3.9)
Specialist	0.4 (0.2-0.7)	0.5 (0.2-1-2)	0.1 (0.0-0.3)	0.1 (0.0-0.6)
Private	1.0 (0.5-2.1)	0.8 (0.2-2.6)	0.8 (0.4-1.9)	0.6 (0.1-2.8)
Hemiarthroplasty volume	1	1 (1-1)	1 (1-1)	0,9999

*Level 1: age, sex, NNIS risk index, fixation, antibiotic prophylaxis, hemiarthroplasty volume, elective/acute surgery, preoperative length of stay, hospital size, region, hospital type and surgical volume. Level 2: hospital

The crude OR for deep SSIs is 0.7 in both hospitals with an annual hospital volume of 150 to 299 THA procedures and of 300 THA procedures or more (table 4). When adjusted for confounders in multilevel analysis, these effects diminish, of which male gender, age ≥80 year, NNIS >1and health care region West showed to be statistically significant.

For deep SSIs in multilevel analysis, we only find a borderline significant protective effect in hospitals with an annual hospital volume of 150 to 299 THA procedures (table 4). For superficial SSIs, the crude OR is 0.4 in hospitals with an annual hospital volume of ≥ 300 THA procedures (table 4). This effect also diminishes when adjusted for confounders, of which NNIS >1 and specialist hospitals showed to be statistically significant.

Table 4 Risk of surgical site infection by hospital volume of primary total hip arthroplasty procedures, reported in Norway between September 1st 2012 and April 30th 2016

		Annual hospital volume		
Infection type		<150	150-299	≥300
Deep surgical site infection	Crude OR	*Ref*	0,7	0,7
	95% CI		0.5-0.9	0.5-0.9
	p-value		0.006	0.007
	Adjusted OR*	*Ref*	0,7	0,9
	95% CI		0.4-1.0	0.5-1.4
	p-value		0.056	0.493
Superficial surgical site infection	Crude OR	*Ref*	0,9	0,4
	95% CI		0.7-1.2	0.3-0.5
	p-value		0,440	<0.001
	Adjusted OR*	*Ref*	1,3	0,8
	95% CI		0.8-2.1	0.4-1.5
	p-value		0.366	0.408

*Level 1: age, sex, NNIS risk index, fixation, antibiotic prophylaxis, hemiarthroplasty volume, elective/acute surgery, preoperative length of stay, hospital size, region, hospital type . Level 2: hospital

6. Discussion

We analyzed national data with a total of 29 746 THA procedures, from 53 private and public hospitals. We found that an annual hospital volume of 150 THA procedures or more may give a lower risk of SSI in multivariate analysis (table 4), but this was not statistically significant. A borderline association was shown between an annual hospital volume of 150 to 299 THA procedures and a lower risk of deep SSIs (table 4).

Muilwijk et al found the same tendency that we found in our study; lower volume giving a higher risk of SSI after THA in the middle hospital volume group, and no significant association between hospital volume and risk of SSI (24). Anderson et al showed the lowest risk of SSI in the middle hospital volume group, and concluded "that hospital surgical volume has an important, complex relationship with rates of SSI in community hospitals" (23). Both studies of Singh et al (22) and Meyer et al (11) found an opposite result to our study, with the highest risk of SSI shown in the middle hospital volume group, but this was not statistically significant. These conflicting results show that we cannot presume that a higher hospital volume is associated with a lower risk of SSI after THA.

Hewitt et al describe a model of how volume may affect quality of surgical care (figure 1), and visualizes how volume as a "proxy" for several risk factors can influence the volume-outcome association in surgical patient care (17). Hewitt's model presents risk factors as the "patient's comorbidity, the specific surgical processes of care with physicians, other clinicians and hospital and organizational skills*"*. Hospital volume can thus be a proxy measure for probable collective experience in a hospital, in a surgery unit and in overall surgical patient care. Higher hospital volume may give experience and develop higher quality skills, and express a multidisciplinary need of experience in specific processes of care (20).

The association between hospital volume and outcome may not necessarily be related to hospital volume of one specific procedure (69). Experience in performing other surgical procedures similar to THA, such as hemiarthroplasty (HA), could be linked to higher quality in performing THA, as there are similarities in overall patient care and surgical techniques,. We found no association with HA in this study, and did not find this in other studies (table 3b).

Charles Vincent defines quality as "the gap between what can be achieved an what actually happens" (25). Hewitt mentions that there is a lack of quality data on health care processes, and suggests that comparable and risk-adjusted outcome-data is the best way of measuring quality of care (17). Accordingly, we should focus on improvements by monitoring SSI as an adverse event after THA procedures, to be able to even out the gap between what should have been and what is, for implementing patient safety. Vincent also describes an adverse event as "an unintended injury caused by medical management*"* (25). Adverse events may be possible systematic errors, and it is important to recognize that quality and patient safety is not merely a personal responsibility, but also a system property (26). Quality is assessed to be more important than hospital size for

distributing health services between hospitals, where national health authorities want to create robust professional teams and increase organizational competence to preserve functions in local hospitals (70). This requires comprehensive background knowledge of surgical procedures, such as THAs and an aim for best practice, and may be illustrated by skills in all processes of surgical care in Hewitt's model (figure 1).

Hewitt's model suggests that we find the risk factors connected to the patient's condition, the procedure in itself and in the organizational context. Vincent et al have similar suggestions in their model for assessing different risk factor types in health care (32, 33). Vincent's model describes more specific factor types and conditions that may cause failure by affecting clinical practice; "the patient, task and technology, individual (staff), team, work environment, organizational and management, and institutional context factors" (33). These two models intertwine and complement each other. Hewitt's model describes several risk factors which may be related to the processes in the pre-, per- and postoperative clinical care (17). Vincent et al elaborates these factors even more for targeted improvement, which may be factors beyond failing skills (33). Vincent's model looks at factors that may influence why these skills were not good enough, such as social factors, communication and workload, and Vincent's model can be used for analyzing risk and patient safety for improvement (33).

Hewitt's and Vincent's models together have similar factors as Zingg et al's model for implementing infection control and surveillance, which range from materials, compliance to guidelines and occupancy, to organizational culture (62). All three models show that there is a multidisciplinary context of risk factors in every part of surgical care.

Patient safety is suggested to be the *"*avoidance, prevention and amelioration of adverse outcomes*"* (25). Several patient, procedure and hospital related risk factors may influence the risk of SSI after THA, and are as such also targeted improvement areas. SSI as a surgical outcome seems to be affected by different structures and processes of care, where volume is a proxy measure for other risk factors we may be able detect in our data, or not. We found that male gender, age ≥80 year and NNIS risk index >1and ≥2 showed a higher risk of developing deep SSI after THA procedure, and with a NNIS risk index >1 and ≥2 SSIs for superficial SSIs (table 3a and 3b). This is supported by Meyer and Muilwijk who also find NNIS and male gender as significant risk factors for hip arthroplasty (11, 24).

By multilevel analysis, we found a significantly lower risk of deep SSI in the Western health care region (table 3b). This region has hospitals represented in all three volume groups, including specialist hospitals. We also found specialist hospitals to have a lower risk of both SSI types, but this was only statistically significant for superficial SSIs (table 3b). Hospitals specializing in orthopedics are shown to have a lower risk of SSI, and hospitals with higher hospital volume and lower SSI rate are described to have an organized and effective infection control (5, 52, 71). An infection control program consists of SSI surveillance, which in itself is associated to decreased SSI rate, and guidelines for infection control (61). Regular feedback to surgeons is shown both to be of significance and not (18, 44). Infection surveillance and other measures of patient safety may be addressed as basics for processes to achieve better quality and safety for THA surgery. If high hospital volume hospitals with lower risk of SSI are better at implementing infection control, it is important to focus on implementing infection control in smaller hospitals as well. A positive organizational culture is suggested to be important for the implementation of an effective infection control in hospitals, which subsequently could affect outcomes like SSIs (61, 62).

Studies by Muilwijk et al (24) and Meyer et al (11) using Dutch and German national infection surveillance data could be comparable with our study in several ways, as they seem to collect much of the same surveillance data. Both studies have volume groups with large differences in the number of procedures, where the highest number of procedure is in the highest volume group. Our study has an even distribution of procedures per volume group for gaining statistical strength. Participation is also voluntary for hospitals in both the Dutch and the German national nosocomial infections surveillance systems, where the Dutch hospitals also can choose which procedures they monitor. Our data is from the period after the Norwegian surveillance system became mandatory, both for continuous registration and for selection of procedures, since September 1st 2012. Meyer's (German) study includes hip replacements due to arthritis and not only primary THA, and this study may therefore not be comparable to ours (11). Anderson et al suggests that their significant association between hospital volume and rates of SSI is due to the high number of procedures, but they include like Meyer et al all hip replacements in their study, and may also not be comparable (11, 23).

Our study has several strengths as it uses national surveillance data (NOIS) with every participating hospital in Norway represented, a high number of THA procedures, and standardized case definitions. NOIS also has a high percentage of registration at follow-up after 30 days (10). Meyer et al did not have a systematically follow up after discharge, which both our study and the

study by Muilwijk et al did (11, 24). Most SSIs manifest within 90 days after surgery (38), and since 2012, NOIS do not follow up SSIs after 30 days registration (37).

We used a two-level (procedure and hospital) multilevel analysis model which is efficient in analyzing hospital data, and as strength in our study, because hospitals may have different environments and cultures that can influence the hospital volume-outcome association (72). Muilwijk's (Dutch) study also used a two-level multilevel analysis model with procedures as level one and hospital as level two (24). In our study we included all confounders (co-variables) in both the multivariate and the multilevel analysis, regardless of p-value, which Muilwijk et al did not (24).

Another strength is viewing superficial and deep SSIs separately. Some studies only examine deep SSIs (23, 52). In our study we expected to find differences between superficial and deep SSIs in our results as there may be different risk factors for superficial and deep SSIs, which we did (table 3a and 3b) (56). Male gender, age ≥80 year and NNIS risk index >1 showed a higher risk of developing deep SSI (table 3a), whereas a lower risk of developing deep SSIs after THA is found in health care region West (table 3b). For superficial SSI NNIS risk index >1 gave a higher risk of SSI after THA, whereas there was a lower risk of developing superificial SSIs in specialist hospitals (table 3b). In the middle hospital volume group we also found differences as in a lower risk of deep SSI and a higher risk of superficial SSIs (table 4), though this was not statistically significant (table 4).

Deep SSIs after THA are probably mainly acquired during surgery or haematogenous (5, 46). Superficial SSIs may be associated with postoperative hematoma or drainage, and can also cause or develop into a deep SSI (5, 47, 51). Superficial SSI is also suggested to be a symptom of postoperative treatment and wound care, rehabilitation stay and the patient's own hygienic care (36). Neither Muilwijk et al or Meyer et al looked at superficial and deep SSIs separately, but they followed the same definitions for SSI as in our study. We found the same trend as Muilwijk et al did in their study with a higher proportion of both deep and superficial SSIs together, in the lowest volume group, but also separately. Their study had a higher rate of SSI in the lowest hospital volume group, which may possibly be due to the lower number of procedures (24).

In this study we wanted to analyze both surgeon and surgical volume as variables associated to the risk of SSIs after THA. As there is no national registration of surgeon volume, we wanted to find

this for our study. In our effort to estimate an average surgeon volume we found that this data would not be sufficient in estimating an association between hospital and surgeon volume and risk of SSI after THA. This is a limitation in our study and a correct calculation of distribution of the number or procedures per surgeon in each hospital is needed. Muilwijk et al used surgeon volume data, and observed a longer duration of surgery and a trend of higher risk of SSI with lower surgeon volume in THA procedures (24). Anderson et al calculated an average annual surgeon volume by the number of procedures each surgeon performed in each hospital, and (23). As we cannot rule out surgeon factor as an important factor in the association between hospital volume and SSIs after THA procedure, we recommend further research for finding reliable surgeon volume data for this.

Several other risk factors that may confound the association between hospital volume and the risk of SSI may not be uncovered, as they are not available in our data or are not available by any surveillance method. We used a prospective cohort design. To identify causality, a randomized design would be the first choice. Other complementary methods of measurement may be; user experience research; adverse events reporting systems, measuring patient safety culture, improvement actions like audits for compliance and surveillance of other outcomes than SSIs.

Possible bias in this study may be clinical diagnostics of superficial SSIs after discharge and registration errors in the hospitals electronic health record systems.

7. Conclusion

Our results seem to be consistent with our models which support our data. They cover a wide range of potential areas of risk factors leading to failures which may give traumatic consequences for the patient and also the staff, and of which we can learn by our mistakes for improvement (6). Hospital volume in itself can presumably not describe quality and patient safety, or predict surgical outcomes such as SSIs. But if hospital volume is an indicator of adverse events and a proxy measure for relevant risk factors, it may, especially together with other available measures of quality and patient safety, help to identify potential areas of improvement (17, 18). Hospitals with lower THA hospital volume should thus be able to perform low risk surgical procedures, if they maintain a good quality of surgical experience, expertise and facilities (8, 69). If practice makes perfect, a higher hospital volume should, as a proxy measure for several factors in surgical

patient care, be a protective factor. Further research is needed to be able to improve quality and patient safety, and to identify the differences in processes and structures of surgical care in hospitals with good outcome versus hospitals with poor outcome of SSIs (19, 73). It seems however to be essential with an implemented effective infection control program (61).

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Article proposal

Original article

Does practice make perfect?

The hospital volume-outcome association in the context of quality and patient safety for total hip arthroplasty

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Abstract

Introduction: Surgical site infection (SSI) is among the most frequent healthcare- associated infections (HAIs) worldwide, and a well-known indicator of quality and safety in hospitals. Several patient-, procedure- and hospital related factors may be of importance to the association between surgical volume and SSI after primary total hip arthroplasty (THA).

Objective: Examine any association between hospital volume and the risk of SSI after THA.

Design: Descriptive cohort-study based on prospective national surveillance data.

Methods: We used surveillance data for THA procedures from the Norwegian Surveillance System for Antibiotic Consumption and Healthcare-associated Infections (NOIS), for the period of September 1st 2012 to April 30th 2016. Multivariate and multilevel analysis estimated any associations between both hospital volume and other co-variables, and the risk of SSIs after THA. The adjusted Odd ratio (OR) was estimated for the hospital volume of THA procedures, stratified in three hospital volume groups: ≤150, 150 to 299, ≥300.

Results: A total of 29746 THA procedures were included from 53 hospitals. We found a borderline statistically significant association between an annual hospital volume of 150 to 299 THA procedures and a lower risk of deep SSI.

Conclusions: Hospital volume in itself can presumably not describe quality and patient safety or predict surgical outcomes such as SSI after THA procedure. As an indicator for adverse events and a proxy measure for other risk factors, hospital volume may help to identify areas of improvement.

Key words: Hospital volume, hip arthroplasty, hip replacement, surgical site infection, infection control.

Introduction

Total hip arthroplasty (THA) is a common procedure worldwide, known to improve the patient's quality of life, relieve pain and improve function and mobility (1-4).There is expected an increase of THA procedures due to growing elderly population (5, 6). Adverse events following THA, such as surgical site infections (SSIs), may however give serious consequences for the patient, healthcare services and socioeconomically (1, 5, 7, 8).

SSI is a well-known indicator of quality and patient safety in hospitals (9, 10). Effective infection control is shown to reduce SSI rates (11). Several risk factors are known to affect the risk of SSIs after THA (1, 9, 12-17), and are essential to know for targeted infection control measures.

Hospital and surgeon volume are suggested as indicators for adverse events after THA procedures, and also to be associated with risk of SSI after THA, but we could not include surgeon volume data as they were not available (18-20). The association between hospital

volume and outcomes such as SSI has been of growing interest since the 1980's, for health providers for managing the health organization and personnel, and also for the patients and politicians (21) . The association between hospital volume and risk of SSIs has been studied with varied results (10, 13, 14, 19, 21-23). Hospital volume is suggested to be a proxy measure for other factors that can affect the risk of SSI, and thus many factors may influence this volume-outcome association (20, 21).

The objective of this study is to examine if there is any association between hospital volume and risk of SSIs after THA, in order to identify potential areas of improvement.

Material and Methods

Data source

We used data from the Norwegian Surveillance System for Antibiotic Consumption and Healthcare-Associated Infections (NOIS - Norwegian acronym), based on the European Centre for Disease Prevention and Control (ECDC) – protocol, Surveillance of SSIs in European hospitals (9, 16). Surveillance in NOIS has been continuous and mandatory since September 1st 2012 (24). NOIS data from five different surgical procedures are submitted from 54 hospitals, both private and public, with THA as one procedure (9, 24). Every four month, data are submitted to a national database at the Norwegian Institute of Public Health (NIPH). National data are quality assured both with validation rules upon import and manual checks. Several risk, background and outcome variables are collected through NOIS (9). NOIS includes a follow up of patients after procedure to record SSI occurring within 30 days after surgery (9, 25).

Study population

This study includes surveillance data of patients who underwent primary THA surgery between September 1st 2012 and April 30th 2016. We excluded data from one hospital which only performed specialized cancer-related THAs (n=14).

Outcome variable

The outcome of interest was physician confirmed SSI. All SSIs are identified in accordance with standardized European definitions of SSI (9, 16, 26). We investigated two outcomes; deep SSIs (deep incisional and organ/space) and superficial SSIs.

Hospital volume of primary total hip arthroplasty (THA)

We studied primary THA which refers to the first time of replacing damaged parts of the whole hip joint by prosthesis (1). Hospital volume was defined as the annual median number of THA procedures performed in each hospital, and in this study primary THA is referred to as THA.

We used NOIS data to calculate a median annual hospital volume where we took into account possible seasonal variations, missing data submission or cessation of THA procedure. For 2012 and 2016, only data from four months was available. We therefore calculated a median hospital volume for those two years based on the complete year for each hospital. We did not find any recommendations regarding the cut offs for hospital volume groups in the literature. We made an equal distribution of the number of THA procedures in each hospital volume group, to gain statistical power. Cut offs were set for hospital volume groups at <150, 150-299 and ≥300 procedures. Our hospital volume data complies with Norwegian Patient Register (NPR - Norwegian acronym).

Co-variables

The following patient and procedure related variables were included; age, sex, NNIS risk index score, antibiotic prophylaxis, elective/acute surgery, fixation method, and preoperative length of stay (LOS). The NNIS risk index is a system to adjust for patients and procedure related factors such as wound contamination class, duration of operation and ASA physical status score (16, 27). ASA is classification of physical status score developed by the American Society of Anesthesiology (16, 27). Structural variables included were hospital type, health care region and hospital size (beds). Hemiarthroplasty (HA) volume was included as a continuous variable.

Data Analysis

We performed separate analyses for superficial and deep SSIs by hospital volume group. Bivariate analysis was used to describe characteristics of hospitals, patients and procedure variables by hospital volume group. We calculated crude and adjusted odd ratio (OR), with 95 % confidence interval (CI) and $p>0.05$ as the statistical threshold, using logistic regression. The lowest hospital volume group was set as reference in all analyses. To model the variations between hospitals, we used multilevel logistic regression with two levels (procedure and hospital) in the final multilevel analysis. All co-variables were included in the final model. All analyses were performed using STATA/SE statistical software package version 14.0 for Windows (StataCorp LP).

Ethics

Consent for using de - identified NOIS data in this study was granted by the Data Protection Official at NIPH (28).

Results

A total of 29746 THA procedures from 53 hospitals are included in this study. A range of 47 to 50 hospitals submitted data to NOIS during the study period, with an annual total of approximately 8000 THA procedures. A national post-discharge follow-up of 97.6% for THAs is recorded in NOIS for this period.

2/3 of all patients undergoing THA surgery are women, and 2/3 of all patients are in the 60-69 and 70-79 age groups (table 1). Mean age is 68 years. 93 % of THA procedures are elective and 94 % of the patients receive antibiotic prophylaxis (table 1). Altogether, 69 % of the patients are in NNIS risk index group 0, and of the 3 % who are high-risk patients, we find more than 50% in hospitals with less than 150 annual THA procedures (table 1).

Table 1 approximately here

Table 2 shows that 30 of the included 53 hospitals are primary, 28 hospitals are located in the South–East health care region, and 29 hospitals have 150 beds or less.

Table 2 approximately here

The highest proportion and number for both deep and superficial SSIs are in hospitals with less than 150 THA procedures annually (table 3).

Table 3 approximately here

Table 4a and 4b approximately here

The crude OR for deep SSIs is 0.7 in both hospitals with an annual hospital volume of 150 to 299 THA procedures and of 300 THA procedures or more (table 5). When adjusted for confounders in multilevel analysis, these effects diminish, of which male gender, age ≥80 year, NNIS >1and health care region West showed to be statistically significant. For deep SSIs in multilevel analysis, we only find a borderline significant protective effect in hospitals with an annual hospital volume of 150 to 299 THA procedures (table 5). For superficial SSIs, the crude OR is 0.4 in hospitals with an annual hospital volume of ≥ 300 THA procedures (table 5). This effect also diminishes when adjusted for confounders, of which NNIS >1 and specialist hospitals showed to be statistically significant.

Table 5 approximately here

Discussion

Our results show that an annual hospital volume of more than 150 THA procedures may give a lower risk of SSI (table 5), but this is not statistically significant in multilevel analysis. However, a borderline significant association is shown between an annual hospital volume of 150 to 299 THA procedures and a lower risk of deep SSIs (table 5).

Norway is a large but sparsely populated country with many smaller hospitals, which makes it difficult to compare with other countries. Despite this, our findings seems to be comparable with findings in another study (14), among several studies examining the relationship between hospital volume and risk for SSIs (5, 13, 14, 19-21, 29). Muilwijk et al shows with Dutch national infection surveillance data, that a lower hospital volume tends to give a higher risk of SSI after THA procedure in the middle hospital volume group, but they found no statistical significant association between hospital volume and risk of SSI (14). This supports the same tendency that we found in our study. Anderson et al found that the lowest risk of SSI were in the middle hospital volume group, and conclude "that hospital surgical volume has an important, complex relationship with rates of SSI in community hospitals" (19). Anderson et al suggest that their significant association is due to the high number of procedures, but they include, like Meyer et al, all hip replacements in their study, and their study results may not be comparable to ours (10, 19). Both studies of Singh et al and Meyer et al found an opposite result to our study, where the highest risk of SSI is shown in the middle hospital volume group, but this was also not statistically significant (23). These conflicting results show that we cannot automatically decide that a higher hospital volume is associated with or equals a lower risk of SSI after THA.

We performed a two-level (procedure and hospital) multilevel analysis, which gives strength to our study. Multilevel analysis is efficient to analyze hospital data, as hospital environments consist of different cultures which may influence a volume-outcome association (30). Our study has several strengths as it uses national surveillance data (NOIS) with every participating hospital in Norway represented, a high number of THA procedures, and standardized case definitions are used. NOIS also has a high percentage of registration at follow-up after 30 days. Meyer et al did not have a systematical follow up after discharge,

which both our study and the study by Muilwijk et al did (10, 14). Most SSIs manifest within 90 days after surgery (31), and since 2012, NOIS does not follow up SSIs after 30 days registration (32).

Hewitt mentions that there is a lack of quality data on health care processes, something we think may be relevant in monitoring for instance staff compliance of surgical procedures and organizational skills in surgical care (21). Hewitt also suggest that comparable and risk-adjusted outcome-data is the best way of measuring quality of care. SSI surveillance is associated with decreased incidence proportion of SSI (11). Together with other methods for measuring patient safety, surveillance can be a basis for improvements of quality and patient safety in surgical care (11). Adverse events may be systematic errors, and it is of importance to recognize that quality and patient safety is not merely a personal responsibility, but also a system property (33).

We found it of importance and as strength for this study to monitor both types of SSIs, and we viewed superficial and deep SSIs separately. Some studies only examine deep SSIs (18-20, 34). We expected to find differences between superficial and deep SSIs in our results as there may be different risk factors for superficial and deep SSIs (table 4a and 4b) (12). In the middle hospital volume group we found a lower risk of deep SSI and a higher risk of superficial SSIs, though this was not statistically significant (table 5). Deep SSIs after THA are probably mainly acquired during surgery or haematogenous (5, 35). Superficial SSIs may be associated with postoperative hematoma or drainage, and can also cause or develop into a deep SSI (5, 17, 36). Superficial SSI is also suggested to be a symptom of postoperative treatment and wound care, rehabilitation stay and the patient's own hygienic care (37).

Hospitals specializing in orthopedics, and thus have a higher hospital volume, show a lower risk of SSIs (34). Some countries has set policies for minimum hospital volumes on the basis of this (10). We also found specialist hospitals to have a lower risk of both SSI types, but this was only statistically significant for superficial SSIs (table 4b), and our results cannot support such actions. Whether hospitals get a higher hospital volume, because patients are more frequently referred to hospitals with better outcome, is not known. Another explanation may be 'practice makes perfect', where experience leads to expertise and can cause a volume-outcome association, our study cannot answer this. Clinical and organizational processes or systems in health care may explain a volume-outcome association (21, 38, 39).

Outcomes are suggested to "reflect structures and processes of care" (38). SSI as a surgical adverse outcome is thus likely to be affected by several structures and processes of care. Hospital volume is also suggested to be a proxy measure for physical and cognitive skills of personnel involved in patient care, and for organizational skills to create effective strategies in surgical care (21). It has been shown that an association between hospital volume and outcome may not necessarily be related to hospital volume of one specific procedure (39). Experience in performing other surgical procedures similar to THA, like hemiarthroplasty (HA), could be linked to higher quality in performing THA, as there are similarities in overall patient care and surgical techniques, but we found no association with HA in this study.

Even though we did not find a statistically significant association between hospital volume and risk of SSI after THA, it has been shown that effective infection control in hospitals is associated with a reduction of SSIs (11). Hospitals with higher hospital volume may be better at developing strategies for improvement and organize their infection control programs due to high activity (5). High volume hospitals may also be defined by status and availability of

surgical experience, expertise and facilities (39). For implementing an effective infection control program, we can imagine that a positive organizational culture is needed, and relate to how organizational factors may affect surgical care in hospitals (11).

Health authorities suggest that smaller hospitals with a sufficient hospital volume are able to perform clinical services of the same quality as larger hospitals (40). The same authorities wish to assign tasks to these smaller hospitals, if they maintain a good quality with competent and trained personnel (40). Any hospital, regardless of volume and size, is supposed to provide sufficient health care. To achieve overall quality and patient safety in surgical procedures, it may be essential to focus on implementing best surgical practice for all hospitals (38). Worry has been expressed that if we specialize hospitals for surgical procedures, only hospitals with high hospital volume will upgrade their surgical experience, expertise and facilities (38).

A limitation in our study is that we despite our effort to include surgeon volume we only have data for hospital volume. Possible bias in this study may be clinical diagnostics of superficial SSIs after discharge and registration errors in the hospitals electronic health record systems.

Conclusion

A borderline association was shown between an annual hospital volume of 150 to 299 THA procedures and a lower risk of deep SSIs. Our result and conflicting results in other studies show that we cannot automatically decide that a higher hospital volume is associated with the risk of SSI after THA.

Hospital volume in itself can presumably not describe quality and patient safety, or predict surgical outcomes such as SSIs. But if hospital volume is an indicator of adverse events and a proxy measure for relevant risk factors, it may, especially together with other available measures of quality and patient safety, help to identify potential areas of improvement (18, 21). Hospitals with lower hospital volume of THA should thus be able to perform low risk surgical procedures, if they maintain a good quality of surgical experience, expertise and facilities (39, 40). If practice makes perfect, a higher hospital volume should, as a proxy measure for several factors in surgical patient care, be a protective factor. Further research is needed to identify the differences in processes and structures of surgical care in hospitals with good outcome versus hospitals with poor outcome of SSIs, in order to be able to improve quality and patient safety. It seems, however, to be essential with an implemented effective infection control program (11).

We recommend further research to find reliable surgeon volume data, because we cannot rule out the surgeon as an important factor in the association between hospital volume and SSIs after THA procedure.

Conflict of interest: None to report.

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Table 1 Number of total hip arthroplasty procedures (%) by annual hospital volume group by patient and procedure variables, reported in Norway between September 1st 2012 and April 30th 2016

	Annual hospital volume			
Variable	Total	<150	150-299	≥300
Age				
0-59	5847 (20)	1936 (20)	1635 (18)	2276 (21)
60-69	9838 (33)	3253 (33)	3021 (34)	3 564 (33)
70-79	9817 (33)	3123 (32)	3 043 (34)	3 651 (33)
≥80	4244 (14)	1544 (16)	1 241 (14)	1 459 (13)
Missing	0	0	0	0
Sex				
Female	19 372 (65)	6300 (64)	5 823 (65)	7 249 (66)
Male	10 374 (35)	3556 (36)	3 117 (35)	3 701 (34)
Missing	0	0	0	0
NNIS risk index				
0	20 523 (69)	5 970 (61)	6 432 (72)	8 121 (74)
1	7 470 (25)	3 135 (32)	1 869 (21)	2 466 (23)
≥2	887(3)	474 (5)	204 (2)	209 (2)
Missing	866 (3)	277 (3)	435 (5)	154 (1)
Elective procedure				
Yes	27 757 (93)	9 078 (92)	8 134 (91)	10 545 (96)
No	1952 (7)	741 (8)	806 (9)	405 (4)
Missing	37 (0)	37 (0)	0 (0)	0 (0)
Preoperative length of stay				
0 days	11864 (40)	4763 (48)	4504 (50)	2597 (24)
1 day	14745 (50)	4281 (43)	3789 (42)	6675 (61)
≥2 days	3131 (11)	807 (8)	647 (7)	1677 (15)
Missing	6 (0)	5 (0)	0 (0)	1 (0)
Fixation method				
Cemented	8 921 (30)	4 290 (44)	1 583 (18)	3 048 (28)
Non cemented	8 532 (29)	2 912 (30)	2 306 (26)	3 314 (30)
Hybrid	12 293 (41)	2 654 (27)	5 051 (57)	4 588 (42)
Missing	0	0	0	0
Antibiotic prophylaxis				
Yes	27857 (94)	8 891 (90)	8 436 (94)	10 530 (96)
No	773 (3)	516 (5)	101 (1)	156 (1)
Missing	1116 (4)	449 (5)	403 (5)	264 (2)

NOTE. Some distributions do not sum up to 100 due to rounding

Table 2 Number of hospitals (THA procedures) by annual hospital volume group by demographic and structural variables, reported in Norway between September 1st 2012 and April 30th 2016

	Annual hospital volume			
Variable	Total	<150	150-299	≥300
Region				
South-East	28 (18218)	15 (4166)	9 (7097)	4 (6955)
West	8 (5416)	4 (1250)	2 (1318)	2 (2848)
Middle	8 (4200)	7 (3053)	0	1 (1147)
North	9 (1912)	8 (1387)	1 (525)	0
Hospital type				
Primary	30 (13590)	22 (6312)	7 (4 997)	1 (2 281)
Secondary	9 (6 935)	4 (1 866)	3 (2 441)	2 (2 628)
Tertiary	7 (4 931)	3 (995)	2 (1 502)	2 (2 434)
Specialist	3 (3 628)	1 (21)	0	2 (3 607)
Private	4 (662)	4 (662)	0	0
Hospital size (beds)				
<=150	29 (11658)	23 (5237)	4 (2814)	2 (3607)
151-350	14 (10568)	7 (3234)	5 (3729)	2 (3605)
>350	10 (7520)	4 (1385)	3 (2397)	3 (3738)

Table 3 Number of primary THA procedures (hospitals), surgical site infections and incidence proportion (95% CI) by annual hospital volume, reported in Norway between September 1st 2012 and April 30th 2016

	Annual hospital volume		
	<150	150-299	≥300
Number of procedures (hospitals)	9856 (34)	8940 (12)	10950 (7)
Superficial SSI-rate (CI 95%)	1.4 (1.1-1.6)	1.2 (1.0-1.5)	0.6 (0.4-0.7)
Number of infections	135	111	61
Deep SSI-rate (CI 95%)	1.3 (1.1-1.6)	0.9 (0.7-1.1)	0.9 (0.8-1.1)
Number of infections	131	81	102

Table 4a Risk of surgical site infection by patient and procedure variables, reported in Norway between September 1st 2012 and April 30th 2016

	Deep surgical site infections		Superficial surgical site infections	
Variable	Crude OR (95% CI)	Adjusted OR* (95% CI)	Crude OR (95% CI)	Adjusted OR* (95% CI)
Age				
0-59	*Ref*	*Ref*	*Ref*	*Ref*
60-69	1.0 (0.7-1.3)	0.9 (0.7-1.4)	1.3 (0.9-1.8)	1.3 (0.9-1.9)
70-79	1.3 (0.9-1.8)	1.2 (0.9-1.8)	1.3 (0.9-1.8)	1.3 (0.9-1.9)
≥ 80	1.6 (1.1-2.3)	1.5 (1.0-2.3)	1.3 (0.9-2.0)	1.3 (0.8-2.0)
Sex				
Female	*Ref*	*Ref*	*Ref*	*Ref*
Male	1.8 (1.4-2.3)	1.8 (1.5-2.3)	1.1 (0.9-1.4)	1.1 (0.9-1.4)
NNIS risk index				
0	*Ref*	*Ref*	*Ref*	*Ref*
1	1.7 (1.3-2.1)	1.5 (1.1-1.9)	1.7 (1.3-2.1)	1.8 (1.4-2.4)
≥2	2.3 (1.4-3.8)	2.0 (1.2-3.5)	3.2 (2.1-5.0)	3.5 (2.1-5.7)
Fixation method				
Cemented	*Ref*	*Ref*	*Ref*	*Ref*
Non cemented	0.9 (0.6-1.2)	0.9 (0.6-1.4)	1.5 (1.1-2.0)	1.4 (1.0-2.1)
Hybrid	0.9 (0.7-1.2)	1.2 (0.9-1.7)	0.9 (0.7-1.2)	0.9 (0.6-1.3)
Antibiotic prophylaxis				
No	*Ref*	*Ref*	*Ref*	*Ref*
Yes	0.7 (0.4-1.3)	0.8 (0.3-2.0)	0.8 (0.4-1.5)	0.7 (0.3-2.0)
Elective procedure				
No	*Ref*	*Ref*	*Ref*	*Ref*
Yes	0.8 (0.5-1.2)	1.1 (0.7-1.7)	1.3 (0.8-2.1)	1.5 (0.9-2.6)
Preoperative length of stay				
0 days	*Ref*	*Ref*	*Ref*	*Ref*
1 day	0.8 (0.6-1.0)	0.9 (0.7-1.3)	0.7 (0.6-0.9)	0.9 (0.7-1.2)
≥2 days	1.1 (0.7-1.5)	1.0 (0.6-1.5)	0.7 (0.5-1.1)	1.6 (0.7-1.8)

*Level 1: age, sex, NNIS risk index, fixation, antibiotic prophylaxis, hemiarthroplasty volume, elective/acute surgery, preoperative length of stay, hospital size, region, hospital type and surgical volume. Level 2: hospital

Table 4b Risk of surgical site infection by demographic and structural variables, reported in Norway between September 1st 2012 and April 30th 2016

	Deep surgical site infections		Superficial surgical site infections	
Variable	Crude OR (95% CI)	Adjusted OR* (95% CI)	Crude OR (95% CI)	Adjusted OR* (95% CI)
Hospital size (beds)				
≤150	*Ref*	*Ref*	*Ref*	*Ref*
151-350	1.2 (0.9-1.5)	1.1 (0.7-1.9)	0.9 (0.7-1.2)	0.6 (0.3-1.1)
>350	1.4 (1.1-1.9)	1.1 (0.4-3.1)	1.1 (0.8-1.5)	0.7 (0.2-2.4)
Region				
South-East	*Ref*	*Ref*	*Ref*	*Ref*
West	0.6 (0.4-0.9)	0.4 (0.2-0.7)	0.9 (0.6-1.2)	0.7 (0.4-1.3)
Middle	1.4 (1.1-1.9)	1.0 (0.6-1.6)	2.0 (1.5-2.7)	1.7 (1.0-3.1)
North	1.0 (0.6-1.6)	0.7 (0.4-1.4)	2.6 (1.9-3.7)	1.5 (0.8-2.9)
Hospital type				
Primary	*Ref*	*Ref*	*Ref*	*Ref*
Secondary	1.0 (0.7-1.3)	0.9 (0.5-1.5)	1.3 (1-0-1.7)	1.9 (1.0-3.8)
Tertiary	1.3 (1.0-1.8)	1.7 (0.7-4.3)	1.0 (0.7-1.3)	1.2 (0.4-3.9)
Specialist	0.4 (0.2-0.7)	0.5 (0.2-1-2)	0.1 (0.0-0.3)	0.1 (0.0-0.6)
Private	1.0 (0.5-2.1)	0.8 (0.2-2.6)	0.8 (0.4-1.9)	0.6 (0.1-2.8)
Hemiarthroplasty volume	1	1 (1-1)	1 (1-1)	0,9999

*Level 1: age, sex, NNIS risk index, fixation, antibiotic prophylaxis, hemiarthroplasty volume, elective/acute surgery, preoperative length of stay, hospital size, region, hospital type and surgical volume. Level 2: hospital

Table 5 Risk of surgical site infection by annual hospital volume of primary total hip arthroplasty procedures, reported in Norway between September 1st 2012 and April 30th 2016

		Annual hospital volume		
Infection type		<150	150-299	≥300
Deep surgical site infection	Crude OR	*Ref*	0,7	0,7
	95% CI		0.5-0.9	0.5-0.9
	p-value		0.006	0.007
	Adjusted OR*	*Ref*	0,7	0,9
	95% CI		0.4-1.0	0.5-1.4
	p-value		0.056	0.493
Superficial surgical site infection	Crude OR	*Ref*	0,9	0,4
	95% CI		0.7-1.2	0.3-0.5
	p-value		0,440	<0.001
	Adjusted OR*	*Ref*	1,3	0,8
	95% CI		0.8-2.1	0.4-1.5
	p-value		0.366	0.408

*Level 1: age, sex, NNIS risk index, fixation, antibiotic prophylaxis, hemiarthroplasty volume, elective/acute surgery, preoperative length of stay, hospital size, region, hospital type . Level 2: hospital

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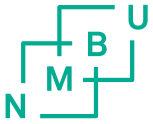

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